

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q88273

Pyare L. SETH

Appln. No.: 10/540,422

Group Art Unit: 1612

Confirmation No.: 4203

Examiner: Lezah ROBERTS

Filed: April 4, 2006

For: PHARMACEUTICAL LIQUID COMPOSITION CONTAINING PYRIDONE DERIVATIVE

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Pyare Seth, hereby declare and state:

THAT I am a citizen of India;

THAT I have received a research degree of Doctor of Sciences in 1955 from the Swiss Federal Institute of Technology School of Pharmacy: and

THAT I am the inventor of the above-identified application and I am familiar with the subject matter thereof.

The following experiment was conducted by me or under my supervision.

Solutions were prepared containing 7% and 10% Pirfenidone dissolved in the solvent mixture containing 50/50 propylene glycol/water as used in all the claimed examples of the Scheiwe et al patent. These solutions were then stored in a refrigerator at 5°C for 24 hours.

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It was observed that the 7% solution remained quite clear, whereas heavy crystallization was found in the 10% solution. This shows that a 10% concentration in this solvent mixture gives a supersaturated solution. Thus, it can be determined that the Scheiwe formulations have poor stability in terms of crystallization.

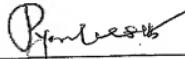
On the other hand, it was surprisingly found that a comparative solution containing 10% Pirfenidone in diethylene glycol monoethyl ether (DGME) as claimed in petitioner's patent application Example 1 of the present invention remained quite clear and did not show any crystallization when stored at low temperatures in a refrigerator at 5°C for 24 hours.

Thus the present compositions show good stability at high concentrations of pirfenidone even at low temperatures.

In my opinion, a person of ordinary skill in the art would not have expected the superior results of the present invention based on the disclosure of Scheiwe et al.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: July 15, 2008.



Dr. Pyare Seth